

PATENTS

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10/662,654

Confirmation No.: 1181

Applicant:

R.L Jenkins et al.

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September 15, 2003

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Docket No.:

09770.105001 SMF

Customer No.:

20786

Title:

Methods and Compositions for the Use of D-Malic Acid to Decrease

Serum Triglyceride, Cholesterol and Lipoprotein Levels

Commissioner for Patents

P. O. Box 1450

Alexandria, VA 22313-1450

February 11, 2004

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Applicant does not believe any fees are due because this paper is being submitted before the mailing of a first Office Action on the merits of the application, as under 37 C.F.R. § 1.97(b)(3). However, if required, the Commissioner is hereby authorized to charge any fees due or credit any overpayment, to Deposit Account No. 11-0980.

Respectfully submitted,

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Application Number	10/662,654				
Filing Date	September 15, 2003	\neg			
First Named Inventor	R.L. Jenkins				
Group Art Unit	Unassigned				
Examiner Name	Unassigned	_			
Attorney Docket Number	09770.105001 SMF				

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			U.S	S. PATENT DOCUMENTS		
Examiner Initials *	Cite No. 1		ent Kind Code if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages / Relevant Figures Appear
	AA	2,972,566		Kitahara et al.	02-21-1961	
	AB	3,063,910		Abe et al.	11-13-1962	
	AC	4,029,812		Wagner et al.	06-14-1977	
	AD	4,076,841		Wagner et al.	02-28-1978	
	AE	4,078,084		Wagner et al.	03-01-1978	
	AF	4,522,811		Eppstein et al.	06-11-1995	
	AG	4,752,616		Hall et al.	06-21-1988	
	AH	4,912,042		Laumen	03-27-1990	
	AI	4,954,514		Kita et al.	09-04-1990	
	AJ	4,965,252		Kuhrts	10-23-1990	
	AK	5,120,766		Holloway et al.	06-09-1992	
	AL	5,155,250		Parker et al.	10-13-1992	
	AM	5,206,247		Regnier et al.	04-27-1993	
	AN	5,262,439		Parthasarathy	11-16-1993	
	AO	5,608,095		Parker et al.	03-04-1997	
	AP	5,627,205		Regnier et al.	05-06-1997	
	AQ	5,705,515		Fisher et al.	01-06-1998	
	AR	5,746,223		Williams	05-05-1998	
	AS	5,783,600		Bisgaier et al.	07-21-1998	
	AT	5,824,449		Ohnishi et al.	10-20-1998	
	AU	5,948,435		Williams	09-07-1999	
	AV	6,004,936		Kisilevsky	12-21-1999	
	AW	6,011,048		Mathvink et al.	01-04-2000	
	AX	6,034,106		Biftu <i>et al</i> .	03-07-2000	
•	AY	6,043,253		Brockunier et al.	03-28-2000	
	AZ	6,090,836		Mams et al.	07-18-2000	
ij	AAA	6,147,250		Somers	11-14-2000	
	AAB	6,193,967	Bl	Morganelli	02-27-2001	

Examiner		Date	
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Submitted for	form 1449/PTO		<u>31</u>		Complete if Known
	{ F	EB 137	1004	Application Number	
IN	FORMATION	DISCL	OSKEE	Filing Date	September 15, 2003
TZ	ATEMENT BY	ARRI	NT	First Named Inventor	Unassigned
	AIEMENI DI	EVALADE	71111	Group Art Unit	Unassigned
Sheet	2	of	3	Attorney Docket Number	09770.105001 SMF

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Í				FORE	EIGN PATENT DOCUMENTS				
Examiner Initials *	Cite No. 1	For Office 3		Code ² known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T6	
	BA	EP	0,348,203	A1	Shionogi & Co.	12-27-1989			
	BB	EP	0,405,788	A2	Shionogi & Co.	01-02-1991			
	BC	EP	0,621,255	A1	Adir et Compagnie	10-26-1994			
	BD	EP	0,763,527	B1	Adir et Compagnie	03-19-1997			
	BE	FR	2130975		Aries	11-10-1972			
	BF	FR	2133024		Aries	11-24-1972			
· ·	BG	FR	2134810		Aries	12-08-1972			
	BH	FR	2140769		Aries	01-19-1973			
	BI	FR	2140771		Aries	01-19-1973	,		
	BJ	FR	2168137		Dynachim	08-31-1973		Y	
	BK	JP	2001/197897		Mitsubishi Chemicals	07-24-2001		Y	
	BL	JP	JP 5271147		Mitsubishi Petrochem	10-19-1993	,	Y	
	BM	WO	95/15760		Merrel Dow Pharmaceuticals	06-15-1995			
	BN	WO	97/15546		Nippon Shinyaku	05-01-1997			
	ВО	WO	98/40375		G.D. Searle	09-17-1998			
	BP	WO	98/51289		Atherogenics	11-19-1998			
	BQ	WO	98/51662		Atherogenics	11-19-1998			
	BR	WO	00/26184		Nematel Dr. Rudolf Eidenschink	05-11-2000			
	BS	WO	00/38725		G.D. Searle	07-06-2000			
	BT	WO	01/70757	A2	Atherogenics	09-27-2001			

	OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS						
Examiner Initials *	Cite No. 1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶				
•	BU	ALAUPOVIC, P., In Handbook of Electrophoresis. Vol. 1, pp. 27-46 (1980).					
	BV	BRADLY, W.A. and Gotto, A.M., American Physiological Society, Bethesda, MD, pp 117-137 (1978)					
~	BW	BROWN, L., et al., "Transdermal Delivery of Drugs," Annual Review of Medicine, 39:221-229 (1988).	T				
	BX	CAREW, T.E., et al., "Antiatherogenic effect of probucol unrelated to its hypochelesterolemic effect: Evidence that antioxidants in vivo can selectively inhibit low density lipoprotein degradation in macrophage-rich fatty streaks and slow the progression of atherosclerosis in the Watanabe heritable hyperlipidemic rabbit," Proc. Natl. Acad. Sci. U.S.A. 84:7725-7729 (1987).					

Examiner		Date	
Signature		Considered	

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Submitted for	form 1449/PTO	_	~ 3 /		Complete if Known
	{ !	FEB 1 3 7	2004 @]	Application Number	
IN	FORMATION	DISCL	OSKĀŽE.	Filing Date	September 15, 2003
TZ	ATEMENT BY	ARRI	UC NT	First Named Inventor	Unassigned
	ALLMENT DI	TALLE	1111	Group Art Unit	Unassigned
Sheet	3	of	3	Attorney Docket Number	09770.105001 SMF

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	-01:	OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS	
Examiner Initials *	Cite No. 1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	CA	DE MEGLIO, P., et al., "New Derivatives of Clofibrate and Probucol: Preliminary Studies of Hypolipemic Activity," Farmaco, Ed. Sci., 40 (11), 833-44 (1985).	
	СВ	DOLPHIN, P. J., "Lipoprotein metabolism and the role of apolipoproteins as metabolic programmers," Can. J. Biochem. Cell. Biol. 63, 850-869 (1985).	
	CC	ENDO, A., "The discovery and development of HMG-CoA reductase inhibitors," J. Lipid Res. 33, 1569-1582 (1992).	
	CD	FOODY, J.M., et al, "HDL cholesterol level predicts survival in men after coronary artery bypass graft surgery: 20-Year experience from the Cleveland Clinic Foundation," Circulation, 102 (19 suppl 3), III-90 to III-94 (2000).	
	CE	GLOMSET J. A., et al, "The metabolic role of lecithin: Cholesterol acytransferase: Perspectives from Pathology," Advan. Lipid Res., 11, 1-65, (1973).	
	CF	GRUNDY, S. M., "HMG-CoA reductase inhibitors for treatment of hypercholesterolemia," <i>New Engl. J. Med.</i> 319, 24-33 (1988).	
	CG	JIN, FY., et al., "Niacin decreases removal of high-density lipoprotein apolipoprotein A-I but not cholesterol ester by Hep G2 cells," Arterioscler. Thromb. Vasc. Biol. 17, 2020-2028 (1997).	
	СН	JIN, FY., et al., "Gemfibrozil stimulates apoliprotein A-I synthesis and secretion by stabilization of mRNA transcripts in human hepatoblastoma cell line (Hep G2), Arterioscler. Thromb. Vasc. Biol., 16, 1052-1062 (1996).	
	CI	MACIEJKO J. J. et al., "Apolipoprotein A-I as a marker of angiographically assessed coronary-artery disease," New England J. Med. 309(7), 385-389 (August 18, 1983).	
	CJ	McCALL, M. R., et al., "Transformation of HepG2 nascent lipoproteins by LCAT: modulation by HepG2 d > 1.235 g/ml fraction," J. Lipid Res., 34, 37-48 (1993).	
	CK	McKENZIE, A., et al., "Optical activation of racemic acid by d-malic acid," J. Chem. Soc., 123, 2875-2880 (1923).	
	CL	MINGPENG, S., et al., "The protective role of high-density lipoproteins in atherosclerosis," Experimental Gerontology, 34 (4) 539-48 (1999).	
	CM	PATSCH, J. R., et al., "Formation of high density lipoprotein ₂ -like particles during lipolysis of very low density lipoproteins in vitro," Proc. Natl. Acad. Sci., 75, 4519-4523 (1978).	
	CN	SICART, R., et al., "Reduction of cholesterol transported in Apo B-rich lipoproteins in spontaneously hypercholesterolemic hamsters fed an apple-supplemented diet," Ann. Nutr. Metab. 31, 1-8 (1987).	
	СО	STEDRONSKY, E. R., "Interaction of bile acids and cholesterol with non-systemic agents having hypocholesterolemic properties," <i>Biochim. Biophys. Acta 1210</i> , 255-287 (1994).	
1	CP	WILSON M. D., et al., "Review of cholesterol absorption with emphasis on dietary and biliary cholesterol," J. Lipid Res. 35, 943-955 (1994).	

3389391_2

Examiner Signature	Date Considered	

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